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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,121	01/13/2000	Ralf Reiner Schumann	0107-020P/GPK	9305

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 04/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/484,121

Applicant(s)

SCHUMANN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 12-14 are pending.

Applicants' amendment filed on January 9, 2002 (Paper No. 17) and Supplemental Response filed December 12, 2001 (Paper No. 16) are acknowledged. Applicant's response has been fully considered. Claims 12-14 have been amended, and claims 15-17 have been cancelled.

Oath/Declaration

2. The new oath/declaration filed February 22, 2002 (Paper No. 19) is acknowledged.

Objection Withdrawn

3. The previous objection of claim 12 is withdrawn in view of applicants' amendment to the claim.

Rejection Withdrawn

Claim Rejections – 35 USC § 112

4. The previous rejection of claims 12-17 under 35 USC § 112, first and second paragraphs regarding human LBP and the variant, mutant or hybrid protein of LBP, is withdrawn in view of applicants' amendment to the claim, cancellation of claims 15-17, and applicants' response at page 2 (Paper No. 17).

Claim Rejections - 35 USC § 102

5. The previous rejection of claims 12, 16 and 17 under 35 U.S.C.102(b) as being anticipated by Scott *et al.* (WO 94/25476), is withdrawn in view of applicants' amendment to the claim, cancellation of claims 16 and 17, and applicants' response at page 2 in Paper No. 17.

6. The previous rejection of claims 12 and 17 under 35 U.S.C.102(b) as being anticipated by Heavner *et al.* (WO 95/08560), is withdrawn in view of applicants' amendment to the claim, cancellation of claim 17, and applicants' response at pages 2-3 in Paper No. 17.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Gazzano-Santoro *et al.* (Infection and Immunity 62, 1185-1191 (1994)).

Gazzano-Santoro *et al.* teach both a recombinant fragment (rBPI₂₃) of a bactericidal/permeability-increasing protein (BPI) and human recombinant LBP (rLBP) can bind lipid A and Escherichia coli J5 bacteria, respectively, and rBPI₂₃ has a higher binding affinity toward endotoxin than rLBP (abstract; page 1187, right column; Figures 1, 2 and 3). In the presence of rLBP, rBPI₂₃ can effectively block the proinflammatory response of peripheral blood mononuclear cells to endotoxin (abstract; page 1188, right column; Figure 4). Therefore, LBP either alone or combined with rBPI₂₃ is used as active component of an agent, which anticipates claim 12. The phrase "for the treatment of septicemia" is an intended use, it does not play any weight in the claimed invention.

In response, applicants indicate the reference only uses rLBP as the standard in a competitive binding assay not as an inhibitor of LPS (page 2, paragraph 5 of the response). The argument is not found persuasive because the claim only recites an agent containing LBP as the

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active agent, it does not indicate LBP acts an inhibitor of LPS, and the phrase “for the treatment of septicemia” does not play any weight in the claimed invention. It appears the reference does indicate rLBP inhibits LPS activity in the chromogenic LAL assay (Fig. 1 at page 1187).

8. Claims 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lengacher *et al.* (J. Inflammation 47, 165-172 (1995/1996)).

Lengacher *et al.* teach recombinant murine and human LBP have been produced using a baculovirus expression system, and LBP can bind free LPS, but only weakly to various live Gram negative bacteria (abstract; pages 167-170; Fig. 3; Tables I and II), which meets the criteria of claims 12-14. The phrase “for the treatment of septicemia” is an intended use, it does not play any weight in the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 12 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Lamping *et al.* (Immune Consequences Trauma, Shock Sepsis, Int. Congr. 4 th, pages 15-19 (March 1997)).

Lamping *et al.* teach human recombinant LBP has been prepared (page 16, paragraph 4; claims 12 and 13) and the binding of wild LBP to LPS has been shown (Fig. 2).

In response, applicants indicate the reference does not teach the use of LBP to inhibit LBP-LPS interaction (page 1 of the supplemental response). The argument is not found persuasive because the claim only recites an agent containing LBP as the active agent, it does not

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indicate LBP inhibits LBP-LPS interaction, and the phrase "for the treatment of septicemia" does not play any weight in the claimed invention.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

April 4, 2002

Christopher S. F. Low
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